K 133026

DEC 3 1 2013

510 (k) Summary

Submitter's information:

Name:	LeMaitre Vascular, Inc.
Address:	63 Second Avenue Burlington, MA USA 01803
Phone:	781-425-1727
Contact Person:	Bryan Cowell, MSc., RAC

Date of preparation:	September 24, 2013
Device Name:	UnBalloon Non-Occlusion Modeling Catheter
Trade Name.	UnBalloon Non-Occlusion Modeling Catheter
Common/ Classification Name:	Catheter, Percutaneous
Classification Panel:	21CFR §870.1250
Class:	II (2)
Product Code:	DQY

Establishment Registration: 1220948

Establishment: LeMaitre Vascular, Inc., 63 Second Avenue, Burlington, MA USA 01803

Owner/Operator: 1220948

Proposed Device Description:

The UnBalloon Non-Occlusive Catheter is a silicone surface coated (medical grade) modeling Catheter with an expandable Nitinol mesh in a retractable sheath. The Nitinol mesh design allows for expansion without occluding blood flow. The Nitinol mesh and radiopaque markers are highly visible under fluoroscopy and assist in the positioning of the device. The inner lumen allows for a 0.035 or 0.038 inch guidewire for over-the-wire access. Side ports and clear handle/luer allow the device and guidewire lumen to be flushed. The blue handle allows the device to be sheathed/unsheathed while the clear handle/luer controls the expansion of the Nitinol mesh.

This submission modifies the current UnBalloon Non-Occlusive Modeling Catheter to be able to deliver higher radial outward force in order to improve stent graft modeling effectiveness (i.e., apposition of the stent graft with the vessel lumen). Additionally, this device modification increases the outer diameter of the thoracic models from 14 Fr to 16 Fr.

Intended Use:

The UnBalloon Non-Occlusive Modeling Catheter is intended to assist in the modeling of self-expanding endoprostheses in large diameter vessels.

Predicate Device:

510(k):	K123531
Device Name:	UnBalloon Non-Occlusion Modeling Catheter
SE Date:	12/14/2012
Regulation Number:	21CFR §870.1250
Device Class Name:	Catheter, Percutaneous
Device Class:	2

510(k):	K121839
Device Name:	UnBalloon Non-Occlusive Modeling Catheter
SE Date:	08/08/2012
Regulation Number:	21CFR §870.1250
Device Class Name:	Catheter, Percutaneous
Device Class:	2

510(k):	K110891
Device Name:	UnBalloon Non-Occlusive Modeling Catheter
SE Date:	09/13/2011
Regulation Number:	21CFR §870.1250
Device Class Name:	Catheter, Percutaneous
Device Class:	2

Substantial Equivalence:

The modified UnBalloon is substantially equivalent to the predicate UnBalloon catheter based on the same intended use and fundamental scientific technological characteristics.

Functional/ Safety testing:

The verification activities conducted on the subject device indicate that the modified UnBalloon Non-Occlusion Modeling Catheter meets the product performance requirements of the device specifications and the modifications presented do not raise additional safety issues.

Sterilization:

The device is validated for ethylene oxide (EO) sterilization according to ANSI/AAMI/ISO 11135-1:2007, "Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization". The Sterilization process remains unchanged.

Biocompatibility:

All blood contact portions of the device were subjected to Biocompatibility testing according to ISO 10993 guidelines for an externally communicating device with limited contact duration (<24 hours), with circulating blood. The biocompatibility assessment established that UnBalloon Non-Occlusion Modeling Catheter is biocompatible.

No new materials are being introduced in the modified UnBalloon and the current biocompatibility tests remains valid.

Summary of Product Testing:

The following tests have been completed to evaluate the performance of the Subject Device the UnBalloon Non-Occlusive Modeling Catheter:

1. Dimensional analysis
2. Apposition length
3. Radial outward force
4. Freedom from leakage
5. Fatigue and simulated use
6. Force at break (i.e., bond strength)
7. Interaction with stent graft materials (light microscope and SEM study)
8. Animal testing (ovine study)

Conclusion:

LeMaitre Vascular has demonstrated that the subject device: the UnBalloon Non-Occlusion Modeling Catheter is substantially equivalent to the predicate device(s) based on its intended use and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 31, 2013

LeMaitre Vascular, Inc.
C/O Bryan Cowell, MSc., RAC
Principal Regulatory Affairs Specialist
63 Second Avenue
Burlington, MA 01803

Re: K133026
Trade/Device Name: UnBalloon Non-Occlusive Modeling Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 25, 2013
Received: November 26, 2013

Dear Mr. Cowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known)	K133026
Device Name	UnBalloon Non-Occlusive Modeling Catheter
Indications for Use	The UnBalloon Non-Occlusive Modeling Catheter is intended to assist in the modeling of self-expanding endoprostheses in large diameter vessels.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___X_____ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

M A Hillebrenner